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M ROBERT KESTENBAUM
11011 BERMUDA DUNES NE
ALBUQUERQUE, NM 87111

EXAMINER	
ROSE, SHEP K	

ART UNIT	PAPER NUMBER
1614	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/529,792	Applicant(s) Ruoslahti
	Examiner Stoble Rose	Group Art Unit 1614

—The MAILING DATE of this communication appears on the cover sheet beneath the corresp ndence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on MAY 1 2002 FOB 10 2003.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-51 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-51 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Stat ment(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Pat nt Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Acti n Summary

The November 5, 2001 Office Action, on page 5, contains not responded to outstanding grounds of rejection of rejection of claims 1 to 8 for obviousness-type double patenting on claims 1 to 8, 11, 12, 14, 17, 20 and 21 of applicants' U.S. Patent No. 6,254,855.

Applicant's May 1, 2002 and Feb 10, 2003 responses are completely non-responsive to these grounds of rejection, which can only be repeated and made FINAL.

The February 10, 2003 response to the outstanding ground of rejection of claims 1 to 11 under 35 U.S.C. 112, first paragraph, based on the fact that there is no written description in the specification of how to make these unusual, (not micronized or spheroidal) anistropic hydroxyapatite (HAP) particles of the claim recited length, width and height is an improper amendment in the specification on page 3, after line 11 to add an improper reference to a foreign patent, WO 98/18719, alleged as describing a method for producing a suspension of HAP.

This ground of rejection can only be repeated and made FINAL.

Applicants may file a RCE that conforms to USPTO policy on Incorporation by Reference, as set forth in MPEP 608.01 (P) (Q), (the referenced source must be a U.S. Patent, i.e. U.S. 6,254,855 based on WO 98/18719).

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the

applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to WO 98/18719 is improper because reference to a foreign application, patent or to a publication, is improper.

The October 1, 2001 amendment and remarks has already informed the reader that Rudin et al WO 98/18719 does correspond to U.S. Patent application 09/297189. However inadvertently the remarks unfortunately failed to inform the USPTO Examiner that the 09/297189 is, in fact, now a patent, Rudin et al U.S. 6,254,855 B1, patented July 3, 2001 with 22 claims including not only claims 1 to 8 to aqueous compositions of "HAP", (hydroxylapatite) particle of overlapped width and length parameters, but also claims 11 and 12, 20 and 21 to toothpastes and chewing gum, and claims 14, 47, to their use in stomatology, (same as herein), which claims raised the issue of obviousness-type double patenting.

The remarks stated that herein, the "HAP" particle is "anisotropically shaped". However this specification while enabling for ultra finely divided HAP particles fails to disclose to persons skilled in the art how to make these anisotropically shaped & HAP particles, as required by statute, 35 USC 112 (1st par.)

The remarks indicate a difference from Rudin '133 (EP 664133-7/25/95-Rudin et al, (Whose HAP particles range in size from 0.015 to 0.06mm) and are ultra finally divided, by a preamble statement of "stomatic application" herein as compared to bone tissue growth stimulation in Rudin "133. However, the term "stomatic" encompasses "to stimulate reparative osteogenesis processors according to the recital of page 2, line 15, page 3, lines 3—4 "osteoreparative" lines 19-20 page 9, lines 8-9, they stimulate reparative osteogenesis.

Exception has been taken to the remarks that the HAP particles herein are anisotropically shaped HAP particles. A careful re-reading of this specification fails to inform the reader how to make anisotropically shaped HAP particles, and " anisotropically shaped" is nowhere mentioned herein.

The method claims Rudin et al U.S. 6,254,855, claims 9, 16, 17, and 20 do enable an anisometric especially bar-like shape to HAP particles according to the recitals of page 3, lines 5, 6.

The written description herein not only fails to describe anisotropically shaped HAP particles, but further fails to describe (or enablement) of how to make these HAP particles of the claim recited length width and height and provide no written description guidance on how to make them.

Claims 1 to 3, 5, 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400(Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breath of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

(2) The state of the prior art

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

(5) The breadth of the claims

(6) The amount of direction or guidance presented

The specification provides no guidance, in the written description. For example, the specification does not provide any written description of how to make these unusually shaped HAP particles, of the claim recited length, width, and height. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488,

20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result. "The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F.2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F.2d 349, 151 USPQ 724.

As stated above, biological activity cannot be predicted a prior but must be determined from the case to case by painstaking experimental study."

(7) The presence or absence of working examples. There are no working examples herein of how to make these unusually shaped HAP particles.

(8) the quantity of experimentation necessary

Activity cannot be predicted a prior but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study".

An update search for U.S. patent application 09/297,189 turned up Rudin et al U.S. 6,254,855 with common applicants to Rudin et al herein; it is available for double patenting obviousness-type, even if the Oct. 17, 1997 priority date herein antedates the May 7, 1998 PCT Pub. date of WO 98/18719 and the June 25, 1999 U.S. filing date of Rudin et al.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 to 3, 5 to 11 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to provide enabling guidance on how to make "anisotropically shaped" HAP particles of the claim recited length width and height.

Claims 1 to 3, 5 to 11 stands rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the argument, in remarks, that these HAP particles are "anisotropically shaped" while the specification nowhere even mentions the term "anisotropically shaped", only "ultra-finely divided" HAP particles, are enabled, being mentioned in the specification, at page 3, line 21, page 5, lines 25 and 26 and in the examples on page 6, 7 and 8.

Claims 1 to 3, 5 to 11 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ultra finely divided HAP particles, does not reasonably provide enablement for anistropically shped HAP particles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The explanation has been provided herein above in this office action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 to 3, 5 to 8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 8, 11, 12, 14, 17, 20, 21 of U.S. Patent No. 6,254,855 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

Claims 1 to 3, 5 to 8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 8, 11, 12, 14, 17, 20, 21 of U.S. Patent No. 6,254,855 B1, taken with anyone of each of:

Rudin et al EP 664133 published July 25, 1995 (by applicants herein) who describes these known ultra finely divided hydroxy appetite particles (0.015-0.6mm).

Sangi LTD, EP 786245, publishes July 30, 1997 who describes these knows ultra finely divided hydroxyapatite particle.

Atsumi et al U.S. 5,833,959, filed January 23, 1997, patented November 10, 1998, which seems to be the U.S. counterpart of Sangi EP 786245, published July 30, 1997, and additionally in view of the dentifrice with hydroxyapatite with particle sizes larger then "ultra finely divided", (as enabled herein), in each of Scheller (I-II), Bristow et al (I-II-III), Coulson (I-II) and Aoki. These are obvious combinations of ingredients, with no showing of criticality of the particle size claimed.

The statement on page 1, first sentence, "—and curing of caries, periadenitis, and paradentosis—" should be revised by deleting –and curing--, and here should be added the three paragraph on the bottom of page 8 and page 9.

The spelling of "chewing gum" should be corrected on page 9, line 6.

Claims 1 to 3, 5 to 8, 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rudin et al EP 664,133 taken with Atsumi et al U.S. 5,833,959 (or Sangi EP 786245) and additionally in view of the admitted prior art set forth on page one of the specification.

It was admitted as prior art on page 1 that dentifrices with the excipients of claims 8 and 10 have been described with larger particle sized hydroxyapatite, and there is no showing of criticality of the particle size claimed.

As noted above, claims 1 to 7 differ from Rudin et al EP 664133 (7/25/95) only by a statement of intended use in the preamble of the composition "for stomatic applications" a term that encompasses dentistry other than oral care as set forth on page 9 of the specification, as in this prior art reference.

Claiming an unpatentable old compound, in combination with a carrier, does not render the combination patentable, if it would be obvious to utilize a carrier with a compound. In re Rosicky, 125 USPQ 341; In re Lerner, 169 USPQ 51; *Ex parte Douros et al,* 163 USPQ 667; and In re Craige, 89 USPQ 609 ; unless the prior art has a negative teaching that the compound was "pharmacologically inert", In re Wiggins, 158 USPQ 199, Ex parte Frohberger, 168 USPQ 376, or, if use of the specific carrier would not be obvious.

The intended use of an old composition does not render composition claims patentable, in re Zierden, 162 USPQ 102, 104, and the mere preamble statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable, In re Sinex, 135 USPQ 302-305.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidal, can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and 308-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

SHEP K. ROSE
PRIMARY EXAMINER

Rose/LR
March 17, 2003